UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BARBARA GAYLE, et al

Plaintiffs,

vs.

PFIZER, INC.; MCKESSON CORPORATION; and DOES 1-50,

Defendants.

CASE NO.: 1:19-CV-03451
HON: WILLIAM H. PAULEY III

PLAINTIFFS' OPPOSITION TO DEFENDANT PFIZER'S MOTION FOR JUDGMENT ON THE PLEADINGS

ORAL ARGUMENT REQUESTED

TABLE OF CONTENTS

Contents

TABLE OF AUTHORITIES

Cases

Rules

Regulations

Plaintiff's Barbara Gayle, et al, by and through their attorneys, Excolo Law PLLC, respond to Defendant Pfizer's motion for judgment on the pleadings as follows:

INTRODUCTION

Plaintiffs bring this action against Defendants for injuries caused through their ingestion of Lipitor. Each of the Plaintiffs was diagnosed with Diabetes subsequently. As discussed in more detail below, Lipitor does not include diabetes as a risk of Lipitor usage. Patients and their healthcare providers were unaware of the risks of using Lipitor. Defendants were aware of thousands of reports of Lipitor and diabetes. To this day, Pfizer considers diabetes to be unexpected for Lipitor and tells that to the FDA.

Defendants bring the instant motion under Fed. R. Civ. P. 12(c), motion for judgment on the pleadings. Defendants argue that Plaintiffs' claims should be dismissed because they are preempted and time-barred among other bases. As will be shown below, Defendants cannot demonstrate at this stage that they are entitled to such relief. Furthermore, Plaintiffs believe that they should be allowed to amend their complaint to address alleged deficiencies raised by Pfizer. If allowed, this will moot Pfizer's motion.

In resolving the instant motion, the Court should look in a stepwise manner. If Plaintiffs are allowed to amend the complaint, the Court should deny Defendant's motion without prejudice pending the amendment. If the Court denies Plaintiff's motion to amend, it should convert the motion to a Fed. R. Civ. P. 56 motion for summary judgment and allow discovery to take place given that Defendants have relied upon documents outside the pleadings and that Plaintiff would require discovery to refute Defendants' arguments. In the event that the Court denies the request to amend and denies the request to convert the motion to a Rule 56 motion and allow discovery,

then Plaintiffs request the Court allow additional time for Plaintiff to respond to the motion using the initial complaint. Irrespective of the above, Plaintiffs respond below to Defendant's preemption argument as best they can, given the lack of discovery.

ARGUMENT

I. PLAINTIFFS SHOULD BE ALLOWED TO AMEND THEIR COMPLAINT

As a threshold matter, Plaintiff respectfully requests leave of the Court to file an amended complaint in response to Defendant's instant motion. Attached as Exhibit "A" to Plaintiffs' opposition is a copy of the proposed amended complaint. This will be the first amended complaint and is being proposed in response to the instant motion.

Plaintiffs originally filed their complaint in the Supreme Court of the State of New York, New York County where Defendant Pfizer maintained their headquarters. The complaint was drafted with New York State Court pleading requirements in mind. Before Plaintiff had a meaningful opportunity to serve the complaint on Pfizer, Pfizer removed the case to this Court. See ECF # 1. Almost immediately, Pfizer filed an answer to the complaint. ECF # 5. On September 16, 2019, Pfizer filed the instant motion for judgment on the pleadings. ECF #21.

As a result of Pfizer's filings, Plaintiffs were denied a meaningful opportunity to amend their complaint as of right. The answer was mostly denials and even to the extent that it raised preemption as an affirmative defense, it was raised in such a generic manner as to not provide Plaintiff a meaningful understanding of the alleged deficiencies in the complaint. Typically, in response to a complaint, a defendant will file a motion dismiss to which a plaintiff will amend their complaint as of right under Fed. R. Civ. P. 15 if necessary as a response. Had Plaintiff originally filed their complaint in federal court, this would have been the likely scenario. Thus, although Plaintiffs could have amended their complaint as of right within 21 days after the answer, as a

practical matter Plaintiff would not have had sufficient understanding of Pfizer's objections to the complaint.

Much of Defendant's motion claims that Plaintiff failed to plead certain elements. For example, on page 14 of their brief, Defendants argue that Plaintiffs have failed to plead fraudulent concealment with sufficient particularity. That is exactly the kind of issue which an amended complaint can remedy.

The Supreme Court has weighed in on amending complaints and has stated:

> In the absence of any apparent or declared reason -- such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. -- the leave sought should, as the rules require, be "freely given."
> *Foman v. Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 230 (1962)

In requesting leave to amend the complaint, Plaintiff has not engaged in any action or inaction suggesting undue delay, bad faith, or dilatory motive. Plaintiffs have never amended the complaint previously and there is no evidence that Plaintiff cannot cure objections raised in Defendant's motion. Furthermore, this is in the early stages of the proceedings and Defendant cannot identify undue prejudice as Plaintiff would typically have an opportunity to respond to a motion to dismiss as of right. Thus, in accordance with *Foman*, this Court should grant leave for Plaintiffs to file the amended complaint attached as exhibit "A".

Given the appropriateness of Plaintiffs' request to amend the complaint, it would be inefficient for Plaintiffs to respond to the instant motion in most regards. In the event that the Court denies Plaintiffs the amended complaint, Plaintiff respectfully requests that the Court allow a reasonable amount of time after such denial to respond to the remaining portions of the complaint.

II. DEFENDANTS MOTION SHOULD BE CONVERTED TO RULE 56

If the Court does not allow the amended complaint which should moot the existing motion, then the motion must be converted to a Fed. R. Civ. P. 56 motion because Defendants have gone beyond the pleadings: "Result of Presenting Matters Outside the Pleadings. If, on a motion under Fed. R. Civ. P. 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." Fed. R. Civ. P. 12(d).

Here, in footnote two on page four of their Brief, Pfizer points to several items that they claim may be reviewed by the Court at the motion to dismiss stage. Specifically, Defendants cite to publicly available FDA data. For example, one of the bases of Defendant claiming they are entitled to dismissal on preemption grounds is that Plaintiffs have failed to provide evidence that Defendant had new or different information concerning the relationship between Lipitor and diabetes. In support of their position, Defendants cite to publicly available materials from the FDA. In making such an argument Pfizer calls into question what information was in the possession of Defendants. At this stage of the litigation, Pfizer has not produced any materials to Plaintiff. It would be unfair to allow Defendants to present this FDA information out of context without internal relevant information being made available to Plaintiffs from Defendants' internal files. Therefore, it is crucial that Plaintiff receive discovery on this topic to refute Defendant's positions.

Therefore, if the Court will entertain Defendants' motion including the references outside the pleading, the Court should either disallow this information and references or convert the motion to a Rule 56 motion and allow Plaintiffs to take discovery.

III. DIABETES IS NOT LISTED IN THE LIPITOR LABEL

To this day, the Lipitor label does not warn for diabetes. Pfizer argues that the 2012 labeling change discussing elevations of HBA1c was adequate to warn doctors of the risk of diabetes. Not so. First, in accordance with 21 C.F.R. § 314.80(a) an unexpected event is defined as:

> *Unexpected adverse drug experience.* Any adverse drug experience that is not listed in the current labeling for the drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the labeling only listed cerebral vascular accidents. "Unexpected," as used in this definition, refers to an adverse drug experience that has not been previously observed (i.e. , included in the labeling) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.

Defendants have failed to show that as a *matter of law*, elevations of HBA1c are synonymous with diabetes. Certainly this is a question of fact that requires expert testimony and is inappropriate for resolution at this stage of the litigation. Even so, common knowledge is that while diabetes involves elevations of HBA1c, not every elevation of HBA1c means diabetes. Thus diabetes is both more specific and more severe that elevations of HBA1c.

If there is any question of the above, Pfizer puts that question to bed through its own actions. On more than 6,000 occasions between July 1, 2012 and June 30, 2015 Pfizer submitted adverse event reports to the FDA involving Lipitor and diabetes on an expedited basis[1]. For each

[1] As Pfizer asserts in footnote 2 on page 4 of their brief, the Court may consider public information from the FDA. The FDA provides to the public extracts of adverse event information reported to the FDA. See https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers. The above assertion is a summary of voluminous materials (the FAERS data) produced in accordance with Fed. R. Evid. 1006.

of these specific reports, Lipitor was defined as the suspect drug and the only adverse event term on the report was diabetes. By definition under 21 C.F.R. § 314.80(c)(1)(i), expedited reports are:

> *Postmarketing 15-day "Alert reports"*. The applicant must report each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but no later than 15 calendar days from initial receipt of the information by the applicant.

Only reports which are unexpected qualify for expedited reporting. On information and belief, Pfizer continues to report diabetes to the FDA as expedited reports.

Thus, given the definition of an unexpected event and that Pfizer reports diabetes to the FDA as an unexpected event, Pfizer should be estopped from arguing that the label adequately warns for diabetes. At a minimum, this raises a question of fact that cannot be resolved at the time of a motion for judgment on the pleadings.

IV. PLAINTIFFS' CLAIMS ARE NOT PREEMPTED

Plaintiffs' claims are not preempted. As discussed above, the label for Lipitor does not and never has warned for diabetes. Furthermore, Defendants are the masters of the label and are required to amend the label as they learn of new information concerning the safety of Lipitor. Defendants argue that because there was a discussion in 2012 concerning elevations of HBA1C that means that the issue of diabetes was resolved for all time. Defendants are incorrect. Furthermore, Defendants have put forth no evidence that they every requested a labeling change adding diabetes to the label. Thus, Defendants cannot show that the FDA would have refused a labeling change that was never requested.

According to the U.S. Supreme Court, warnings are not simply present or absent, they evolve over time:

> As the FDA explained in its notice of the final rule, 'newly acquired information' is not limited to new data, but also encompasses 'new analyses of previously submitted data.' The rule accounts for the fact that risk information accumulates over time and that the same data may take on a

> different meaning in light of subsequent developments: "[I]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'
>
> *Wyeth v. Levine*, 555 U.S. 555, 569 (U.S. 2009) (citations omitted).

The *Wyeth* Court further opined:

> But absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.
>
> *Id. at 571*

More recently, the Supreme Court reaffirmed the holdings of *Wyeth* and further set forth what is meant by clear evidence:

> For that reason, we have previously held that "clear evidence" that the FDA would not have approved a change to the drug's label pre-empts a claim, grounded in state law, that a drug manufacturer failed to warn consumers of the change-related risks associated with using the drug. See *Wyeth* v. *Levine*, 555 U. S. 555, 571, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009). We here determine that this question of pre-emption is one for a judge to decide, not a jury. We also hold that "clear evidence" is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning.
>
> *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019)

Here Pfizer presents no evidence that it ever asked the FDA for a labeling change with respect to Lipitor and diabetes. Nor is there any evidence that Pfizer enhanced the warning on the label via changes being effected as allowed under 21 C.F.R. § 314.70. As discussed above, Pfizer continues to consider diabetes an unlabeled event for Lipitor and any argument that the label is adequate should be estopped by Pfizer's actions.

Pfizer's reliance on *Merck* is misplaced. *Merck* stands for the proposition that rulings on preemption are to be made by the judge. Even so, there are factual questions that must be addressed as a component of any decision on preemption. More to the point, *Merck* reaffirms *Wyeth* in that the burden is on the proponent of preemption that the FDA would have rejected a labeling change. Pfizer has not and cannot meet this demanding standard.

Pfizer then argues that Plaintiff has failed to show that there is sufficient evidence to include diabetes in the label. As discussed above diabetes is both more serious and more severe thank elevations of HBA1c. One key failure of this argument is that the standard for including an adverse event in the "adverse event" section is lower than the standard for placing the event in the "warnings" section. Surprisingly Pfizer makes a misrepresentation to the Court at the top of page 9 of their brief. This Court should not be bamboozled. The correct standard to add something to the adverse event section of the report comes from 21 C.F.R. § 201.57(7) which states:

> *Adverse reactions.* This section must describe the overall adverse reaction profile of the drug based on the entire safety database. For purposes of prescription drug labeling, an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is ***some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.*** (emphasis added).

To add something to the adverse event section does not require "reasonable evidence of a causal association with the drug" as stated by Pfizer. This is a much lower standard. Certainly, if there is a basis to believe that Lipitor can increase HBA1c, there is a basis to believe it can cause or contribute to diabetes.

In any event, there is certainly a question of fact as to whether the receipt of thousands of adverse event reports concerning diabetes was sufficient to enhance the Lipitor label. What is not

in dispute is that Pfizer never made the change and never asked the FDA. Absent such evidence, Pfizer's motion must be denied.

V. THE COURT SHOULD NOT CONSIDER PFIZER'S MOTION WITH RESPECT TO NEW YORK STATUTES OF LIMITATION AT THIS TIME

Should the Court allow Plaintiffs to amend the complaint as discussed above, Pfizer's motion with respect to statute of limitations will need to be revised. In the event that the Court does not allow the amended complaint, Plaintiffs respectfully request a reasonable amount of time after the denial to respond.

VI. THE COURT SHOULD NOT CONSIDER PFIZER'S REMAINING ISSUES AT THIS TIME

Should the Court allow Plaintiffs to amend the complaint as discussed above, the remaining portion of Pfizer's motion will need to be revised. In the event that the Court does not allow the amended complaint, Plaintiffs respectfully request a reasonable amount of time after the denial to respond.

CONCLUSION

For the above reasons, this Court should respectfully (1) allow Plaintiffs' amended complaint; (2) deny with prejudice Pfizer's motion with respect to preemption; (3) deny the remainder of Pfizer's motion without prejudice pending the amended complaint; and (4) if the Court denies Plaintiffs' request to amend the complaint, allow Plaintiff a reasonable amount of time to respond to Pfizer's motion other than preemption. In the event that the Court will not deny Pfizer's motion on its face, because Defendants have gone beyond the pleadings, the Court should convert this motion into a Rule 56 motion for summary judgment and allow sufficient discovery to allow Plaintiff to properly respond to such motion.

Dated: October 30, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 30, 2019, I caused the foregoing Memorandum in Opposition to Defendants' motion for judgment on the pleadings to be filed electronically with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

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